K080187

MAY - 9 2008

510 (k) Summary
Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps

Company Name and Address:

Olsen Medical
3001 West Kentucky Street
Louisville, KY 40211
Phone (502) 772-4280
Fax (502) 772-4282

Contact Information:

John Waters
Director of Quality & Regulatory Affairs
Olsen Medical
3001 West Kentucky Street
Louisville, KY
Telephone (502)772-4280
Facsimile (502)772-4282
Email johnw@olsenmedical.com

Device Classification:

Electrosurgical Cutting and Coagulation Device & Accessories are Class II devices per 21 CFR 878.4400

Statement of Substantial Equivalence:

Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps are substantially equivalent to Q2 Medical's Bayonet Forceps Bipolar Irrigating (K002752) and Dermacare's Disposable Bipolar Cord and Bipolar Forceps (K884656) based on the device's similarity to the predicated device in intended use, materials, design, and functionality. Both of these predicate devices were owned, manufactured and marketed by Olsen Medical.

Indications for Use:

The **Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps** (Catalog No. 20-0XXX) is a single use product sold sterile and is intended for use in electrosurgery for coagulation and irrigation of tissue. This device is intended for use with the OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing.

EXECUTIVE SUMMARY

Description

OLSEN MEDICAL Single Use Bayonet Bipolar Irrigating Forceps is packaged sterile with a nonpyrogenic fluid pathway. It consists of an inlet pathway running into a transparent rigid PVC tube attached to the right hand prong of the bayonet forceps. This gives the surgeon a visual of the fluid pathway which facilitates the local fluid irrigation through the forceps. The device is for Single Use Only and is designed for use with bipolar electrosurgical units.

Indications for Use

The **Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps** (Catalog No. 20-0XXX) is a single use product sold sterile and is intended for use in electrosurgery for coagulation and irrigation of tissue. This device is intended for use with the Olsen Medical Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing.

Please read the instruction manuals supplied with the irrigation module and the bipolar coagulator or electrosurgical systems before using this product.

Summary of Performance Testing

The new device is technologically the same as the predicate device. Device qualification criteria meet or exceed the minimum qualification criteria for the predicate device. The device conforms to applicable ASTM and ISO Standards. Tests will meet the applicable requirements of ANSI/AAMI HF18:2001 and IEC 60601-2-2 3rd Edition.

Device Comparison Table

The attached table shows the differences and similarities between the Olsen Medical Integrated Irrigation Tubing and Bipolar Cord Set and the predicate device. This table supports our claim of substantial equivalence.

Device Comparison Photographs

The attached photographs of the predicate and the new device support our claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Olsen Medical
% Mr. John P. Walters
Director of Quality & Regulatory
Affairs
3001 West Kentucky Street
Louisville, Kentucky 40211

Re: K080187
Trade/Device Name: Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 21, 2008
Received: April 25, 2008

Dear Mr. Walters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps

Indications For Use:

The **Olsen Medical Single Use Bayonet Bipolar Irrigating Forceps** (Catalog No. 20-0XXX) is a single use product sold sterile and is intended for use in electrosurgery for coagulation and irrigation of tissue. This device is intended for use with the OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set or similar design of Bipolar Cord and Irrigation Tubing.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil RP Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080187